DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-159/S-001

Medicis Pharmaceutical Corp.
Attn.: R. Todd Plott, M.D.,
V.P., Clinical Research and Regulatory Affairs
8125 N. Hayden Road
Scottsdale, AZ 85258

Dear Dr. Plott:

Please refer to your supplemental new drug application dated August 25, 2003, received August 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Loprox® Shampoo (ciclopirox), 1%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a new 10 mL container for the physician's sample package, which falls outside of the approved range of package sizes. Draft carton and container labeling for the proposed package size were included in the supplement.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the approved labeling text.

The final printed labeling (FPL) for the immediate container and carton labels must be identical to the draft immediate container and carton labels submitted in the supplement dated August 25, 2003.

Please submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – NDA." Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case later than the next Annual Report. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-159/S-001." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jacqueline Smith, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Wilson H. DeCamp
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approved